



General Assembly

Amendment

January Session, 2017

LCO No. 8842



Offered by:
SEN. LEONE, 27th Dist.

To: Subst. House Bill No. **7118** File No. 793 Cal. No. 525

(As Amended by House Amendment Schedule "B")

"AN ACT CONCERNING BIOLOGICAL PRODUCTS."

1 Strike everything after the enacting clause and substitute the
2 following in lieu thereof:

3 "Section 1. Section 20-619 of the general statutes is repealed and the
4 following is substituted in lieu thereof (*Effective October 1, 2017*):

5 (a) For the purposes of section 20-579 and this section:

6 (1) "Biological product" has the same meaning as provided in 42
7 USC 262;

8 [(1)] (2) "Brand name" means the proprietary or trade name selected
9 by the manufacturer and placed upon a drug product, its container,
10 label or wrapping at the time of packaging;

11 [(2)] (3) "Generic name" means the established name designated in

12 the official United States Pharmacopoeia-National Formulary, official
13 Homeopathic Pharmacopoeia of the United States, or official United
14 States Adopted Names or any supplement to any of said publications;

15 (4) "Interchangeable biological product" means a biological product
16 that: (A) The federal Food and Drug Administration has licensed and
17 determined to meet the standards for interchangeability pursuant to 42
18 USC 262(k)(4), or (B) is therapeutically equivalent to another biological
19 product, as set forth in the latest edition of or supplement to the
20 federal Food and Drug Administration's publication "Approved Drug
21 Products with Therapeutic Equivalence Evaluations";

22 [(3)] (5) "Therapeutically equivalent" means drug products that are
23 approved under the provisions of the federal Food, Drug and
24 Cosmetic Act for interstate distribution and that will provide
25 essentially the same efficacy and toxicity when administered to an
26 individual in the same dosage regimen;

27 [(4)] (6) "Dosage form" means the physical formulation or medium
28 in which the product is intended, manufactured and made available
29 for use, including, but not limited to, tablets, capsules, oral solutions,
30 aerosol, inhalers, gels, lotions, creams, ointments, transdermals and
31 suppositories, and the particular form of any physical formulation or
32 medium that uses a specific technology or mechanism to control,
33 enhance or direct the release, targeting, systemic absorption, or other
34 delivery of a dosage regimen in the body;

35 [(5)] (7) "Epilepsy" means a neurological condition characterized by
36 recurrent seizures; and

37 [(6)] (8) "Seizures" means a disturbance in the electrical activity of
38 the brain. [; and]

39 [(7) "Antiepileptic drug" means a drug prescribed for the treatment
40 of epilepsy or a drug used to prevent seizures.]

41 (b) Except as limited by subsections [(c), (e) and (i)] (f), (h) and (l) of

42 this section, unless the purchaser instructs otherwise, the pharmacist
43 may substitute a generic drug product with the same strength,
44 quantity, dose and dosage form as the prescribed drug product which
45 is, in the pharmacist's professional opinion, therapeutically equivalent.
46 When the prescribing practitioner is not reasonably available for
47 consultation and the prescribed drug does not use a unique delivery
48 system technology, the pharmacist may substitute an oral tablet,
49 capsule or liquid form of the prescribed drug as long as the form
50 dispensed has the same strength, dose and dose schedule and is
51 therapeutically equivalent to the drug prescribed. The pharmacist shall
52 inform the patient or a representative of the patient, and the
53 practitioner of the substitution at the earliest reasonable time.

54 (c) Except as limited by subsections (f), (h) and (l) of this section,
55 unless the purchaser instructs otherwise, the pharmacist may
56 substitute a biological product for a prescribed biological product if:
57 (1) It is an interchangeable biological product, and (2) the practitioner
58 has not specified, in the manner described in subsection (f) of this
59 section, that there shall be no substitution for the prescribed biological
60 product.

61 (d) (1) Prior to the dispensing of an interchangeable biological
62 product to a patient, the pharmacist shall inform the patient or a
63 representative of the patient of a substitution of an interchangeable
64 biological product for a prescribed biological product. Not later than
65 forty-eight hours after dispensing the interchangeable biological
66 product, the pharmacist shall make an entry documenting compliance
67 with this subdivision in the patient's medical or pharmacy record, and
68 (2) prior to delivering an interchangeable biological product to a
69 patient through mail, shipment or parcel delivery service, the
70 pharmacist shall contact the patient or a representative of the patient
71 by telephone and inform the patient or representative when the
72 interchangeable biological product will be delivered and confirm that
73 the patient or representative will be present for the delivery. Delivery
74 of the interchangeable biological product shall not be made unless the
75 patient or a representative of the patient acknowledges such delivery

76 in writing. Not later than forty-eight hours after contacting the patient,
77 the pharmacist shall make an entry documenting compliance with this
78 subdivision in the patient's medical or pharmacy record.

79 (e) Upon the dispensing of an interchangeable biological product,
80 but not later than forty-eight hours following the dispensing of such
81 product, the pharmacist shall inform the prescribing practitioner by
82 facsimile, telephone or electronic transmission of the substitution of
83 such interchangeable biological product for a prescribed biological
84 product.

85 ~~[(c)]~~ (f) A prescribing practitioner may specify in writing or by a
86 telephonic or other electronic communication that there shall be no
87 substitution for the specified brand name drug product or prescribed
88 biological product specified on any prescription form, provided (1) for
89 written prescriptions, the practitioner shall specify on the prescription
90 form that the drug product or prescribed biological product is "brand
91 medically necessary" or "no substitution", (2) for prescriptions
92 transmitted by telephonic means, the pharmacist shall specify "brand
93 medically necessary" or "no substitution" on the prescription form in
94 the pharmacist's handwriting or in the electronic prescription record
95 and shall record on the prescription form the time the telephonic
96 authorization was received and the name of the person who
97 communicated the telephonic authorization to the pharmacist, and (3)
98 for prescriptions transmitted by any other electronic communication,
99 the practitioner shall select the dispense as written code on the
100 certified electronic prescription form to indicate that a substitution is
101 not allowed by the practitioner. No prescription form for written
102 prescriptions, and no prescription form for prescriptions transmitted
103 pursuant to subdivision (2) or (3) of this subsection, may default to
104 "brand medically necessary" or "no substitution".

105 ~~[(d)]~~ (g) Each pharmacy shall post a sign in a location easily seen by
106 patrons at the counter where prescriptions are dispensed stating that,
107 "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS
108 EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE

109 BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY
110 EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR
111 UNLESS YOU DO NOT APPROVE." The printing on the sign shall be
112 in block letters not less than one inch in height.

113 [(e)] (h) A pharmacist may substitute a drug product under
114 subsection (b) or interchangeable biological product under subsection
115 (c) of this section only when there will be a savings in cost passed on to
116 the purchaser. The pharmacist shall disclose the amount of the savings
117 at the request of the patient.

118 [(f)] (i) Except as provided in subsection [(g)] (j) of this section, when
119 a pharmacist dispenses a substitute drug product as authorized by
120 subsection (b) of this section or an interchangeable biological product
121 as authorized by subsection (c) of this section, the pharmacist shall
122 label the prescription container with the name of the dispensed drug
123 product or interchangeable biological product. If the dispensed drug
124 product or interchangeable biological product does not have a brand
125 name, the prescription label shall indicate the generic name of the drug
126 product or the nonproprietary name of the interchangeable biological
127 product dispensed along with the name of the manufacturer of the
128 drug [manufacturer or distributor] product or interchangeable
129 biological product.

130 [(g)] (j) A prescription dispensed by a pharmacist shall bear upon
131 the label the name of the drug or biological product in the container
132 unless the prescribing practitioner writes "DO NOT LABEL", or words
133 of similar import, on the prescription or so designates in an oral or
134 electronic transmission of the prescription.

135 [(h)] (k) Neither the failure to instruct by the purchaser as provided
136 in subsection (b) of this section nor the fact that a sign has been posted
137 as provided in subsection [(d)] (g) of this section shall be a defense on
138 the part of a pharmacist against a suit brought by any such purchaser.

139 [(i)] (l) Upon the initial filling or renewal of a prescription that
140 contains a statistical information code based upon the most recent

141 edition of the International Classification of Diseases indicating the
142 prescribed drug is used for the treatment of epilepsy or to prevent
143 seizures, a pharmacist shall not fill the prescription by using a different
144 drug manufacturer or distributor of the prescribed drug or biological
145 product, unless the pharmacist (1) provides prior notice of the use of a
146 different drug or biological product manufacturer or distributor to the
147 patient and the prescribing practitioner, and (2) obtains the written
148 consent of the patient's prescribing practitioner. For purposes of
149 obtaining the consent of the patient's prescribing practitioner required
150 by this subsection, a pharmacist shall notify the prescribing
151 practitioner via electronic mail or facsimile transmission. If the
152 prescribing practitioner does not provide the necessary consent, the
153 pharmacist shall fill the prescription without such substitution or use
154 of a different drug or biological product manufacturer or distributor or
155 return the prescription to the patient or to the patient's representative
156 for filling at another pharmacy. If a pharmacist is unable to contact the
157 patient's prescribing practitioner after making reasonable efforts to do
158 so, such pharmacist may exercise professional judgment in refilling a
159 prescription in accordance with the provisions of subsection (b) of
160 section 20-616. For purposes of this subsection, "pharmacy" means a
161 place of business where drugs and devices may be sold at retail and for
162 which a pharmacy license was issued pursuant to section 20-594,
163 including a hospital-based pharmacy when such pharmacy is filling
164 prescriptions for employees and outpatient care, and a mail order
165 pharmacy licensed by this state to distribute in this state. "Pharmacy"
166 does not include a pharmacy serving patients in a long-term care
167 facility, other institutional facility or a pharmacy that provides
168 prescriptions for inpatient hospitals.

169 (m) Not later than forty-eight hours following the dispensing of an
170 interchangeable biological product, the dispensing pharmacist or the
171 pharmacist's designee shall make an entry of the specific product
172 provided to the patient, including the name of the product and the
173 manufacturer of the product. The entry shall be made in a manner that
174 provides notice to the prescriber and may be made through one of the

175 following means: (1) An interoperable electronic medical records
176 system, (2) an electronic prescribing technology, (3) a pharmacy benefit
177 management system, or (4) a pharmacy record. If the entry is not made
178 by any of the means specified in subdivision (1), (2), (3) or (4) of this
179 subsection, the pharmacist shall communicate the product dispensed
180 to the prescriber using either facsimile, telephone or electronic
181 transmission, provided such communication shall not be required
182 when a refill prescription is not changed from the product dispensed
183 on the prior filling of the prescription. The provisions of this
184 subsection shall not apply to interchangeable biological products
185 dispensed by a pharmacy operated by a hospital licensed in
186 accordance with the provisions of chapter 368v.

187 (n) Each prescription for a biological product that is delivered to a
188 patient through mail, shipment or parcel delivery service shall contain
189 a written notice to the patient detailing the specific biological product
190 being shipped, the name of the pharmacist or pharmacy providing the
191 prescription and contact information, including, but not limited to, a
192 telephone number the patient may call if he or she has questions
193 regarding the prescription.

194 [(j)] (o) The commissioner, with the advice and assistance of the
195 commission, shall adopt regulations, in accordance with chapter 54, to
196 carry out the provisions of this section.

197 Sec. 2. (NEW) (*Effective October 1, 2017*) Prior to prescribing a
198 biological product, as defined in section 20-619 of the general statutes,
199 as amended by this act, a prescribing practitioner shall discuss with the
200 patient or a representative of the patient the treatment methods,
201 alternatives to and risks associated with the use of such biological
202 product. The prescribing practitioner shall document such discussion
203 in the patient's medical record not later than twenty-four hours after
204 such discussion has taken place."

This act shall take effect as follows and shall amend the following sections:

Section 1	<i>October 1, 2017</i>	20-619
Sec. 2	<i>October 1, 2017</i>	New section